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Subject Environmental Defense comments on 3,3'-Dichlorobenzidine  
Dihydrochloride (CAS# 612-83-9)

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Environmental Defense appreciates this opportunity to submit comments on the robust  
summary/test plan for **3,3'-Dichlorobenzidine Dihydrochloride (CAS# 612-83-9)**.

The Color Pigments Manufacturers Association, Inc., (CPMA), in response to EPA's  
High Production Volume (HPV) Chemical Challenge, has submitted a test plan and  
robust summaries for 3,3'-dichlorobenzidine dihydrochloride (DCB).

According to this submission, DCB is used as a closed system intermediate in the  
manufacture of organic color pigments. No other uses, if any, are mentioned.  
However, it is unclear whether DCB can be considered a closed system intermediate  
under the HPV Challenge. The submission indicates that DCB is not produced in this  
country, but is apparently used here, in which case it must be transported from its  
site(s) of import to its site(s) of use and it is thereby subject to risks that might be  
encountered in the process of its receipt, transport and unloading at the site of use.  
None of these activities are described in this submission.

DCB has a long history of use and is a well-known carcinogen. Thus, it is a data rich  
chemical. A brief computer search for 3,3'-dichlorobenzidine resulted in over 30,000  
hits. Many of these "hits" are publications in peer reviewed scientific journals that  
discuss various aspects of its use and toxicity. Therefore, it is likely technically correct  
to state that virtually every SIDS element required under the HPV Challenge "was  
obtained from a reputable journal". However, a serious disregard of the intent of the  
HPV Challenge is indicated by the failure to provide any data or discussion to address  
the respective SIDS element or to cite appropriate sources of this information in the text  
or reference section of the test plan.

The robust summaries of this submission provide the very minimum data to address  
each SIDS element and, as discussed below, are frequently inconsistent with the test  
plan.

Specific comments:

1. The structure of DCB on page 6 of the test plan is incorrect. The structure shown has chlorine atoms in the number 2 positions, whereas they should be at the number 3 positions. Also, the structure shows a double bond between the rings, which is not the case.
2. There may be a problem with formatting, but the first chemical name provided for DCB on page 6 of the test plan runs into the second. They should be clearly separated.
3. The test plan appears to contradict itself in that on page 3, DCB is said to be completely reacted so that no free DCB remains in the finished product, while on page 6 it is stated that low levels of DCB observed in studies with animals are thought to have been derived from impurities in the pigment tested. This DCB is attributed to "mono-azo impurities", but that is not confirmed. It could have been un-reacted DCB.
4. The robust summaries are frequently inconsistent with the test plan. In the test plan a number of required SIDS elements are said to be addressed by data generated by computer estimates, whereas the robust summaries state that these SIDS elements were determined experimentally.
5. In at least one case, the robust summary states that the data were generated with "unnamed surrogate substances". There is no way from this vague description to determine if the surrogate chemical used is a suitable substitute for DCB.
6. The studies of toxicity to mammals are dated, were not conducted under GLP and in at least one case were conducted with substances of unknown purity. In spite of these obvious deficiencies, the sponsor claims that the study was considered "Reliable without restriction".
7. The description of developmental toxicity provided in the robust summaries directs the reader to the study of repeated dose toxicity. On review of the repeated dose toxicity study, no description of any study of developmental toxicity is provided.
8. No information is provided to address the SIDS element for reproductive toxicity in the robust summaries, yet the test plan states that this element is addressed by data from an unreferenced reputable journal.

In summary, given the wealth of information on DCB in the open literature, it is disappointing to see such a poorly prepared submission as this. There is no way it can be considered adequate to address the requirements of the HPV Challenge.

Thank you for this opportunity to comment.

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